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EXAMINER

BLIZZARD, CHRISTOPHER JAMES

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. This office action is in response to preliminary amendment files 5/17/10. As directed claims 49, 65, 72, 76 and 95 were amended, claim 64 was cancelled, and no claims were added. Therefore this application currently has claims 49-63 and 65-95 pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 49-59, 61-63, 65, 66, 68-70, 72, 73, 76-82, 84-89, and 91-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Hills (6,482,391).

4. Regarding claims 49 and 65, Hills discloses a delivery device for a medicament comprising a housing (fig. 1), a receptacle (5) for holding a medicament in the form of a powder (column 3, lines 46-53), a source of propellant (4) in the form of a canister of gas (fig. 2), wherein the housing has an inlet (11) and an outlet (12) for the receptacle, wherein the inlet is in fluid communication with the source of propellant (fig. 2) and the inlet is directed against the medicament (fig. 2) and the outlet is spaced from the medicament to allow aerosolization of the medicament (fig. 2), wherein the outlet pathway contains a choke in the form of the diameter of the outlet pathway constricting due to a turn in the pathway which would decelerate the medicament (fig. 2, around #13).

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5. Regarding claims 50 and 51, Hills discloses the receptacle and the source of propellant being removable from the housing (column 3 ,lines 58-60).
6. Regarding claims 52 and 53, Hills discloses a fluid pathway (9) between the inlet and the source or propellant, having a choke (fig. 2, around #7) in the form of a restriction that would decelerate the flow of propellant.
7. Regarding claims 54-57, Hills discloses the inlet being an inlet tube extending into the receptacle having an end directed toward the medicament with a flared opening or perforation (fig. 2).
8. Regarding claims 58 and 59, Hills discloses the receptacle having a bottom containing the medicament and a top which connects to the housing and the outlet is arrange to open into the receptacle at the top of the receptacle and is substantially flush with the top of the receptacle (column 4, lines 7-10).
9. Regarding claim 61, Hills discloses the outlet being formed as a hole in the housing which is in fluid communication with an outlet pathway in the housing which connects to the exterior of the housing (fig. 2, path between 12 and 14).
10. Regarding claim 62, Hills discloses a stable aerosol of medicament being formed upon activation of the device (column 4, lines 11-15).
11. Regarding claim 63, Hills discloses the device wherein the outlet is normally sealed by a valve until a critical pressure is reached (column 4, lines 18-21).
12. Regarding claim 66, Hills discloses the device having a mouthpiece (14).
13. Regarding claim 68, Hills discloses the device being a handheld device (column 4, lines 19-21).

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14. Regarding claims 69 and 70, Hills discloses the canister of gas having a valve (6), and inherently could be arranged above the canister since the device is handheld and its orientation can be easily manipulated.

15. Regarding claims 72 and 73, Hills discloses the claimed housing and receptacle of medicament in the delivery device above.

16. Regarding claims 76-82, 84-89, and 91 Hills discloses the claimed dispensing receptacle; header unit, in the form of the housing; and source of propellant in the above claims.

17. Regarding claim 92-94, Hills discloses the claimed delivery device housing having a first open ended compartment which the source of propellant (4) is received in (fig. 2), and a clip is adapted to receive the dispensing receptacle (column 3, lines 58-60), wherein the clip is associated with a propellant exit connection (7) and the exit connection is arranged to engage with an entry connector (10) for the dispensing receptacle (fig. 2).

18. Regarding claim 95, Hills discloses the method of dispensing medicament as an aerosol to a patient comprising the steps of, providing a receptacle (5) containing powder medicament, discharging pressurized propellant from a canister (4) through a delivery tube (11) extending into the receptacle and directed at the medicament, forming an aerosol by transfer of energy from the propellant to the powder (column 4, lines 14-15), and discharging the aerosol through an outlet passage (12)

Claim Rejections - 35 USC § 103

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19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 60, 75, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hills (6,482,391).

21. Regarding claims 60 and 83, Hills discloses the claimed device except for the outlet not extending into the receptacle, but does disclose the outlet only extending partway in the receptacle (column 4, lines 7-9). It would have been an obvious matter of design choice to have the out not extend into the receptacle, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

22. Regarding claim 75 Hills discloses the claimed invention except for the receptacle and the propellant canister being linked together. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the receptacle and the propellant canister be linked together, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. Howard v. Detroit Stove Works, 150 U.S. 164 (1893).

23. Claims 67 and 90 rejected under 35 U.S.C. 103(a) as being unpatentable over Hills (6,482,391) in view of Sladek (6,014,972).

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24. Regarding claims 67 and 90, Hills disclose the claimed device but does not disclose the mouthpiece (14) being a tube for engaging with a breathing tube for a patient using a respirator. Sladek teaches a device for adapting an inhaler for engaging with a breathing tube for a patient using a respirator (Abstract, lines 1-3). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device of Hills with an adapter for engaging an inhaler with a breathing tube of a respirator as taught by Sladek in order to provide the advantage of delivering medication to a patient being mechanically ventilated.

25. Claims 71 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hills (6,482,391) in view of Wetterlin (4,114,615).

26. Regarding claims 71 and 74, Hills discloses the claimed device except for the receptacle being in the form of a plurality of blister packs. Wetterlin teaches a powder medicament device wherein the receptacle is a plurality of blister packs (column 4, lines 59-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide dispenser of Hills with blister packs as taught by Wetterlin in order to provide the advantage of being able to better control the amount of medicament delivered to the user.

Response to Arguments

27. Applicant's arguments filed 5/17/10 have been fully considered but they are not persuasive. Applicant's argument that the feature of Hill around #13 does not constitute a choke is not persuasive because the feature around #13 comprises a bend in the fluid pathway which would inherently inhibit the flow of liquid by decelerating it.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday-Friday, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Christopher Blizzard /
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771